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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,276	08/09/2000	H. Craig Dees	PHO-113	4947

7590

03/08/2005

Cook Alex McFarron Manzo Cummings & Mehler Ltd
200 West Adams Street
Suite 2850
Chicago, IL 60606

EXAMINER

EPFS FORD, JANET L

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/635,276

Applicant(s)

DEES ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7-10,12-19,21-23,25,27-30,32-34,36 and 37 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3,5,7-10,12-19,21-23,25,27-30,32-34,36 and 37 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 09 August 2000 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1-14-2005; 9-03-04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 1-3, 5, 7-10, 12-19, 21-23, 25, 27-30, 32-34, and 36-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter).

In the response filed 9-03-04, Applicants amended the instant claims to recite wherein the claimed pharmaceutical compositions and medicaments are “to be photoactivated within less than 24 hours following application,” and wherein the method of treating comprises illuminating said human or animal tissue with light “within less than 24 hours following said applying to photoactivate said halogenated xanthene present within or proximate to said tissue.” However, the specification as filed provides support for only 0-72 hours and 0-1 hour. In comparison to the teachings of the specification as filed, the newly added limitation which requires “photoactivation within less than 24 hours” reads beyond the specification teaching of “0-1 hours”, and particularly reads on from 2 hours to less than 24 hours. In regards to the specification teaching of 0-72 hours, the newly added limitation of less than 24 hours, now specifically reads away from 24 hours to 72 hours. The specification as filed does not provide specific guidance and/or support for the range of photoactivation within less than 24 hours.

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Although, this particular range of "within less than 24 hours" overlaps the ranges of 0-1 hour and 0-72 hours, the newly added limitation is not immediately envisioned from the teachings of the specification as filed.

When filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP § 714.02 and § 2163.06 ("Applicant should * * * specifically point out the support for any amendments made to the disclosure.") Therefore, since Applicants do not specifically provide direct support for the current amendment to the claims Applicant's amendment is considered new matter. Applicants must cancel all new matter in response to the instant Office action.

Claim Rejections - 35 USC § 102

3. Claims 1-3, 7-8, 10, 21-23, 27-28, and 36-37 remain rejected and claims 9 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. for the reasons of record set forth in the Office Action mailed 3-01-2004.

4. Applicant's arguments filed 9-03-2004 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Williams et al. does not disclose or suggest the invention of the amended claims of the present application because Williams et al. fails to teach specific targeting by any photosensitizing agent, and the illumination step taught by Williams et al. must be performed after a latency period of 1-7 days in order to allow excess photosensitizer to clear from adjacent (and healthy) tissue.

The examiner recognizes that Williams et al. does not expressly teach that the disclosed method for photodynamic therapy comprises photoactivation within less than 24 hours following application. However, in regards to the claimed compositions, to the extent that Williams et al.

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discloses photodynamic therapy compositions comprising photosensitising agents that are useful as an alternative to traditional chemotherapy and surgical treatments (see col. 1, lines 13-18), wherein exemplary agents include (*inter alia*) Rose Bengal (550 nm activation wavelength; see col. 5, lines 5-14), Williams et al. is considered to anticipate the instant claims. Applicants argue that since the instant composition claims have been amended to recite wherein photoactivation of the compounds occurs within less than 24 hours following application, Williams et al. no longer anticipates the instant claims. However, the newly added limitation neither adds nor subtracts any structural element from the claimed compositions, therefore despite the recitation of the intended use of the claimed invention, the newly added limitation does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Moreover, Applicants argue that Williams et al. does not disclose or suggest the claimed invention since the use of the terms photosensitizers and photodynamic therapy in Williams is incorrect and inconsistent with the teachings of the present application and with the use of these terms by those of ordinary skill in the art. According to Applicants although Williams et al. makes cursory mention of Rose Bengal as a so-called photosensitizing agent the reference fails to disclose or suggest photodynamic pharmaceutical compositions or medicaments containing Rose Bengal as that term is defined in the present application and recited in independent Claims

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1, 13, 17, 21, 32, 36 and 37 of the present application. Contrary to Applicant's assertions, Williams et al. disclose Rose Bengal (550 nm activation wavelength; see col. 5, lines 5-14) as an exemplary photosensitizing agent, and further discloses that the photosensitising agents of are brought into contact with the vascular tissue in target lesions by topical application or direct injection into the target tissue, and are administered in formulations, suitable formulations will be in combination with penetrating solvents in the form of a gel, lotion, cream, or ointment containing a sufficient amount of the light sensitising agent (col. 5, lines 33-52). Therefore, despite Applicant's arguments, topical formulations comprising Rose Bengal are clearly disclosed by the teachings of Williams et al. Although, Williams et al. does not particularly disclose Applicant's intended use of the claimed compositions, the compounds of Williams et al. meet all the structural requirements of the instantly rejected product claims.

Furthermore, Applicant's argue that Williams et al. mere mention of the term "Rose Bengal" as a photosensitizing agent does not through linguistic imprecision, disclose the claimed invention. This is especially true as Applicants have very precisely claimed their invention and do not merely recite a photosensitizer. According to Applicants The Photonics Dictionary, 49th International Edition (2003), provides several meanings that apply to both photothermal and photodynamic therapy, Williams et al. inclusion of Rose Bengal in a list of photosensitizing agents suitable for photocoagulation does not disclose or suggest the claimed invention. Again, contrary to Applicant's assertions, despite the difference in the intended use of the prior art compositions, the difference in intended use does not materially influence the structure of the claimed composition. As stated above, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA

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1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Moreover, Applicant's reliance upon a post-filing definition of the term photosensitizer is inappropriate since the definition that Applicant is relying upon was not available as of the time of filing of the instant application, not the publication year of The Photonics Dictionary, 49th International Edition is 2003, and the instant application has a filing date of 8/09/2000.

Finally, Applicants argue that the Williams disclosure is fundamentally contrary to that of the present application, since Williams describes dye-mediated photocoagulation and briefly mentions Rose Bengal, while Applicants have described and claim a photodynamic medication consisting of a halogenated xanthene, one of which is Rose Bengal. Once again, despite the difference in use of compositions comprising Rose Bengal, Williams et al. clearly discloses a composition comprising Rose Bengal, and therefore is considered to anticipate Applicant's claimed invention since Applicant's intended use is not considered to merit any patentable weight that would distinguish the instant invention from the prior art.

5. In addition to the above discussion, Claims 9 and 29 are also considered to be anticipated by the teachings of Williams et al. to the extent that the formulations of Williams et al. which are disclosed in combination with penetrating solvents, are considered as being disclosed in tissue penetrating solvents since the formulations are intended to for use in treating vascular tissue by topical application or by direct injection. As stated in the prior Office Action, the photosensitising agents of Williams et al. are brought into contact with the vascular tissue in target lesions by topical application or direct injection into the target tissue, and are administered in formulations, suitable formulations will be in combination with penetrating solvents in the form of a gel, lotion, cream, or ointment containing a sufficient amount of the light sensitising

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agent (col. 5, lines 33-52). Topical formulations contain a sufficient amount of the photosensitising compound to be effective in photodynamic therapy. Generally, concentrations in the range of 0.001 to 25 wt. %, preferably from about 1 to 5 wt. %, may be used (see col. 7, lines 7-11).

Claim Rejections - 35 USC § 102

6. Claims 1, 3, 5, 10, 12-13, 21, 23-26, 30, 32 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Goers et al.

7. The instant rejection was previously withdrawn by the Examiner in response to Applicant's amendment to the claims to remove the term "antibodies" in the response filed 10-06-2003. However, to the extent that the term "ligand" as recited in claims 5 and 25 may encompass an antibody, the teachings of Goers et al. anticipate the claimed invention. The examiner considers claim 5 which recites wherein the halogenated xanthene is coupled to at least one chemical or biological targeting moiety, to be inconsistent with claim 1 that recites wherein the pharmaceutical composition consists of a halogenated xanthene. However, the prior art is applied to the extent that the prior art discloses a composition *comprising* a halogenated xanthene coupled to a ligand, in particular an antibody. The examiner applies the instant prior art based upon the interpretation that the claimed compositions "consists of" wherein the halogenated xanthene is the photoactive component.

Goers et al. disclose the use of photochemicals including photosensitizers, wherein said photosensitizers include xanthenes and in particular Rose Bengal, as therapeutic agents (col. 20, lines 50-55). Additionally, in another embodiment, Goers et al. teach that antibodies may be covalently attached to the therapeutic agents (i.e. photosensitizers including Rose Bengal; Rose

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Bengal is photoactivated using light at a wavelength of between 500nm to 600 nm see specification as filed at page 20, Table 1) through an intermediate linker (see col. 21, lines 9-13). Moreover, Goers et al. teach that the antibody or antibody fragment of the antibody therapeutic agent conjugate functions to deliver the conjugate to the target site, i.e. the antibody functions as a targeting moiety (see col. 28, lines 5-17). Moreover, Goers et al. describe the use of the antibody-therapeutic agent conjugate in photoradiation therapy, which encompasses the treatment of disorders by combining the phototoxic effects of the photosensitizer and the site-specific attachment of the antibody to a target site. The photosensitizer is activated by a light source and its cytotoxic effect is mediated through the production of singlet oxygen, which results in toxicity to neighboring cells (col. 28, lines 45-68).

8. Claims 1-3, 5, 7-8, 10, 12-19, 21-23, 25, 27-28, 30, 32-34 and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Watson (US Patent No. 5,053,006).

9. The instant claims are drawn to a topically-applicable photodynamic pharmaceutical compositions, and the use thereof, consisting of a halogenated xanthene as the photoactive component, in particular wherein the halogenated xanthene is Rose Bengal, and further wherein said pharmaceutical composition is to be photoactivated less than 24 hours following application, and wherein said pharmaceutical composition is useful for the treatment of diseases of human and animal tissue. According to the specification as filed at the bridging paragraph between pages 8-9, a "topically-applicable form" of the halogenated xanthene medicaments of the present invention includes wherein the compound is formulated in a liquid. Therefore, to the extent that the prior art discloses halogenated xanthene compounds in a liquid formulation, the prior art is interpreted as reading on the claimed "topically-applicable" pharmaceutical compositions.

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Additionally, to the extent that the term "ligand" may encompass an antibody, the following prior art is considered to read on claims 5 and 25.

Watson discloses a 0.9% saline solution of rose Bengal at 30 mg/ml (see col. 8, lines 56-58). Moreover, Watson describes the use of Rose Bengal solution in a method comprising simultaneous photoactivation (i.e. irradiation) with exposure to Rose Bengal (see col. 6, lines 14-16). Watson also teaches that erythrosine B can be used as a photosensitizer (see col. 7, lines 24-26) in the same manner as Rose Bengal. Watson has also attached erythrosin B to an endothelial antibody, and further teaches that erythrosin B bound to isothiocyanate is commercially available (see col. 4, lines 14-23).

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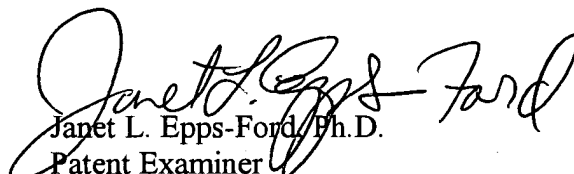
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Janet L. Epps-Ford, Ph.D.
Patent Examiner
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JLE